K040325

MAR - 8 2004

510(k) Summary of Safety and Effectiveness (In accordance to 21 CFR §07.87(b))

Device Name

Proprietary Device Name : PNM 60.

Establishment Name and Registration Number of Submitter

Name: MEDIBELL, MEDICAL VISION TECHNOLOGIES LTD
Registration: 3003809739
Corresponding Official: Dan Laor
MATAM
Haifa, 31905
Israel

Device Classification

Classification Code:	86 HKI
Regulation Number:	886.1120
Panel Identification:	Ophthalmic
Classification Class:	Class II Product

Reason for 510(k) Submission

Modification of a legally marketed device. Special 510(K)

Identification of Legally Marketed Equivalent Devices

K001111 Panoret 1000A

Device Description

The PNM 60 is a modification of the legally marketed Panoret 1000 A K001111 Digital Retinoscope. It is based on transcleral illumination. Its optics distinguishes the illumination path from the imaging path, thus, enables non mydriatic wide angle imaging. The Panoret viewing angle has been changed from (Panoret 1000A) 100 degrees to PNM 60 degrees

Intended Use of Device

The PNM 60 is a diagnostic device indicated to provide digital photographs of the interior of the eye as well as the anterior segment and external part of the eye.

Safety & effectiveness information

Panoret PNM device is designed to comply with the requirements of the IEC-60601-1 safety standard.
Brightness control: The relative spectral radiant power distribution and the photometric luminance have been changed. The device built–in light controls and the device operation have been adjusted to compensate for the modification.

Substantial Equivalency

It is Medibell opinion that the PNM 60 is substantially equivalent in terms of safety and effectiveness to the legally marketed Panoret 1000A K001111.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2004

Medibell Medical Vision Technologies Ltd.
c/o Dan Laor, General Manager
MATAM
Haifa, 31905
Israel

Re: K040325
Trade/Device Name: PNM 60
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: February 5, 2004
Received: February 17, 2004

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040325

DEVICE NAME:

INDICATION FOR USE: The PNM 60 is a diagnostic device indicated to provide digital photographs of the interior of the eye as well as the anterior segment and external part of the eye.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Dennis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K040325

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)